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1. Your reference

P3067

2. Patent applicatior
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25 JUL 1998

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

HUNTLEIGH TECHNOLOGY PLC
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BEDFORDSHIRE
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Patents ADP number *(if you know it)*

50690700 1

If the applicant is a corporate body, give the country/state of its incorporation

UNITED KINGDOM

4. Title of the invention

PNEUMATIC SYSTEMS

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

GROUP IPR DEPARTMENT
HUNTLEIGH TECHNOLOGY PLC
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Patents ADP number *(if you know it)*

50690700 3

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

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Number of earlier application	Date of filing *(day / month / year)*

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a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
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YES

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Continuation sheets of this form	/
Description	12
Claim(s)	/ 3
Abstract	/
Drawing(s)	2 + 2

10. If you are also filing any of the following, state how many against each item:

Priority documents	/
Translations of priority documents	/
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Request for preliminary examination and search *(Patents Form 9/77)*	/
Request for substantive examination *(Patents Form 10/77)*	/
Any other documents *(please specify)*	/

11. I/We request the grant of a patent on the basis of this application.

Signature Shalini Thaker Date 23 JULY 1998

12. Name and daytime telephone number of person to contact in the United Kingdom TRACEY LONG (01582) 745811

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PNEUMATIC SYSTEMS

This invention relates to pneumatic systems and in particular to pneumatic systems having an inflatable and/or deflatable article connected to a fluid source, for example a pump.

It is known for such systems to have a coupling assembly connecting the article to the fluid source, the coupling assembly comprising a male insert and a cooperating female receptacle for receiving the male insert so as to form a coupled state. The male insert or female receptacle includes a mechanical latch cooperating with a cavity on a corresponding surface of the other for mechanically latching and unlatching the coupling assembly, the male insert member and the female receptacle both defining a pathway for the flow of fluid through it when in the coupled state. A seal member extends between the male insert member surface and the surface of the female receptacle to provide a fluid tight seal when in the coupled state.

WO96/14785 describes a pneumatic system comprising an inflatable mattress connected to a pump by a connector mounted on the end of a fluid line from the inflatable mattress which becomes mechanically inoperable upon disconnection with the pump. In this way, the connector ensures that the inflatable mattress is used only once, for reasons of clinical safety.

Modern technology has now made it possible to design the pump to be programmable so that a number of different inflatable articles with differing inflating and/or deflating arrangements fulfilling totally different functions may be attached to a physically identical pump.

However, pneumatic systems of the prior art thus far include connectors which prevent re-use but which are not able to distinguish between different articles to be inflated or different pumps and there is a need for an intelligent means associated with the pump and/or the article which is able to identify or distinguish between the pump and the article connected, and further to control the operation of the pump with respect to the pressure and flow against time, appropriate to the article connected.

Accordingly, the invention provides a pneumatic system including a pump and inflatable and/or deflatable article, connection means for connecting the article and pump for fluid flow therethrough, wherein the pump and article have respective communication means, each said means capable of exchanging information or energy to identify the article and to operate the inflation and/or deflation of the article by the pump accordingly.

Preferably, the information exchange between the article and the pump may comprise information contained in the article communication means being read by the pump communication means and used to operate the pump, or more preferably, information contained in the article communication means being read by the pump communication means, and information modified/generated within the pump communication means being stored within the article communication means during use. The information exchange may be by means of an energy source which may include but not be limited to electrical, pneumatic, acoustic, magnetic, electromagnetic or optical signals.

The modified information or energy transmitted to the pump is used to identify the article and thereafter

used to control the pump operation either without user interface or to signal the user to operate the pump as indicated. Thus, operation of the pump may be altered automatically to match the requirements of the article to be inflated and/or deflated and its application.

Preferably, the information may include specific information, i.e. codes, to identify the article and/or its mode of operation (including pressure and flow versus time profile, and alarm settings) and/or security markings, to prevent unauthorised use.

In a preferred embodiment, the communication means on the article is located within the connection means connecting the article to the pump.

Examples of information contained within the article communication means may include some or all of the following data:-

Article serial number - for traceability in the event of customer complaint, product modification, recall or product ownership.

Article manufacturing date - the pump communication means can automatically infer that an article with a limited storage time from manufacture to use is out of time and therefore will not operate the pump, indicating so on the operator panel. This would be relevant to the case of single use sterile articles where the sterile packaging has a limited lifetime.

Article type information - The pump communication means reads the code and identifies the code as that to be used by the pump and sets up the correct pressure and flow versus time profiles on the air delivery paths automatically. Also the communication means on the pump can indicate to the user on the pump operator panel which

application or applications the pump/article combination is intended for.

Single use/re-use information - Indicates to the pump communication means to display on the operator panel whether the connected article is designed for re-use or for single use only.

Duration of use information - this could either be in the form of the article in-use running hours or number of pressure time cycles per use or the actual times recorded when used. If this information is fed by the pump communication means back to the article communication means then it can be read by any pump communication means on subsequent usage. In this way users can be signalled when articles have reached the end of their operating life and for either clinical efficacy or safety reasons should no longer be used and whether user compliance of prescribed therapy has been administered. Also, the pump could be automatically shut-off or instructed to give appropriate warnings at the end of operating life/use.

Single Use Information - If the article communication means indicates application for single use only then the pump communication means can input in the article communication means, an indication that the article has already been used. On subsequent attempts to use the article the pump communication means will recognise single use has occurred and not operate. In this case the clinical efficacy and safety of a single use article can be preserved automatically.

Limited or Multiple Re-use - If this is indicated within the article communication means then the pump communication means will automatically clock up the

number of use cycles, put the information into the article communication means, and when the designed number of use cycles has been reached, the pump can automatically indicate this to the user so preserving clinical safety and efficacy.

Re-usable clinical articles after being re-processed (consequent to use to eliminate cross-contamination between users) - Here the pump communication means looks for an indication from the article communication means that the article has been validly reprocessed between use cycles. This validity information is placed in the article communication means at the reprocessing facility using an approved piece of equipment. In this way only approved reprocessing which maintains clinical efficacy and safety will be accepted by the pump for use.

The use of communication means within a pneumatic system is applicable to any article to be inflated and/or deflated by a pump. Our interest, especially with respect to the information exchange outlined above, is in their use in the field of intermittent compression therapy and pressure area care when such pneumatic systems may comprise (i) a pump and inflatable/deflatable compression garment(s) wrapped around a user's limb(s) and (ii) an inflatable/deflatable mattress providing pressure relieving or pressure reducing support to a user lying thereon. Therefore, in the preferred embodiments of the invention, the article may be a compression garment(s) or an inflatable/deflatable mattress.

The use of communication means as described above will result in fewer individual pump models being required for different pneumatic performance levels and operator interfaces. This will lead both to

manufacturing economies of scale and substantial acquisition, storage and inventory cost reductions, which is particularly beneficial in the case of compression garments and inflatable mattresses within cost sensitive and resource limited healthcare establishments.

The communication means can be separately applied to pumps and to the articles so long as the air delivery path configurations are functionally compatible. Thus pumps could operate articles yet to be developed so long as the articles have their operating characteristics configured in a compatible communication means attached thereto.

In a healthcare environment this use of communication means prevents the inadvertent and unsafe operation of pump types with inflatable articles which are not functionally safe or clinically compatible. A pump equipped with the communication means will readily deliver safe, effective therapy with a wide range of inflatable articles.

The communication means of the present invention for information exchange between the article and the pump to control operation of the pump may comprise conventional read and write information systems; examples of which, include bar code, magnetic stripe coding, a connector insertion/rotation when connecting the article to the pump; geometry or intensity of magnetisation or transmissive or reflective optical path read by sensors; unique combinations of mechanical shapes read by mechanical switches or electronic memory chip with memory retention without power such as flash memory or EPROM or UV EPROM.

A preferred embodiment of the present invention is described below, by way of example only, with reference to the accompanying drawings in which:

Figure 1 shows a schematic diagram of a communication means according to the present invention;

Figure 2 shows an alternative method of mounting one element of the communication means to that in Figure 1; and

Figure 3 shows a typical radio communication means comprising a passive transponder and powering radio circuit.

Referring to Figure 1, the preferred embodiment consists of a pneumatic system consisting of a compression garment 21 connected to a pump 20 by a connector 10. The connector 10 has a connector part 11 connected to the pump 20 and a cooperating connector part 12 connected to the fluid line of the garment 21. The connector 10 carries a radio frequency identification device 30, i.e. a transponder. The transponder 30 is mounted on the connector part 12 connecting the compression garment 21 to the pump 20 and a corresponding radio circuit is located within the pump 20. The radio transponder 30 is in the shape of an annular ring fitted to the connector part 12 surrounding its fluid line outlet. The transponder 30 typically comprises a coil acting as an antennae to transmit and receive signals, a capacitor to temporarily store energy to power the transponder, an integrated circuit to provide control and modulation functions and a read/write electronic memory (EEPROM). The transponder 30 is used to transmit and receive information to and from the pump radio circuit 31. As shown in Figure 3, radio circuit 31 in the pump

comprises coils located close to the pump outlet to provide for transponder power and two-way communication between the transponder 30 and the circuit 31. The transponder 30 is passive and does not need any power to store information. It is energised by coming into proximity with the coils of the radio circuit 31 in the pump 20 and can then communicate with the pump circuit 31. As the transponder 30 does not need power to store information there is no need for connection cables or batteries and it may be completely sealed after assembly, within connector part 12 attached to the compression article 21.

The communication between the transponder and pump is controlled by hardware and software within the pump.

The operation of the pump is programmable, specifically the operation in terms of applied pressure and flow versus time profiles and alarm monitoring. This is achieved by having the key parameters which control this operation stored in the transponder 30 to be read by the radio circuit in the pump and used to operate the pump accordingly. Thus by changing the garment the operation of the pump may be changed and hence the pump may be programmable by the garment.

The general approach is for the pump software to signal to the transponder via the radio link a request to transmit certain operational parameters. These are received by the pump radio link and used as a basis to operate the pump. For example, if the pressure is specified for the article then the pump will provide that particular pressure.

It is the information stored in the transponder within the connector on the article which indicates to the pump to operate accordingly.

Specific examples of parameters include:

Operating parameters - operating pressure level, pressure versus time inflation rate, pressure versus time deflation rate, duration of inflation, duration of period between inflation's.

Alarm parameters, the pressure at which an inflation characteristic is detected, time at which this is tested, number of fault conditions prior to alarm occurring. This would be duplicated for each alarm condition.

In use, the connector parts 11,12 are joined together. The transponder 30 within the garment connector part 12 when coming into the vicinity of the pump's radio circuit 31 is powered and responds by transmitting a signal to the pump radio circuit 31. The radio circuit 31 may request further information from the memory of the transponder 30 or it may modify some of the transponder memory 30. The pump 20 processes the information it has read from the transponder 30 and accordingly provides the specific inflation requirements for that garment 21.

The pump 20 is reconfigured after any break in its operation, for reasons of it being switched off, powered off or another garment being connected.

The radio circuit 31 reads the information within the transponder 30 memory on the connector part 12 of the garment 21 and identifies the garment 21 and if the information is compatible with that held within the pump 20 either electronically or within the software, then the pump operates the garment 21 according to the information transmitted by the transponder 30. In the case of single-

use garments, the transponder memory may contain additional control information which instructs the pump not to re-inflate or not to inflate after a certain time or any other parameter based decision process. Additionally, the radio circuit 31 may modify the transponder 30 memory to prevent further re-use of the garment 21 upon re-connection with the or another pump.

The pump 20 may be configured so that it is solely dependent on the transponder 30 memory to provide information regarding the inflation requirements of the garment 21 attached. This allows for new garments to be connected and operated by the pumps without the pumps' having to be upgraded.

The pump radio circuit and transponder could exchange information about the following:

The transponder in the garment could be used to store information about the pump's own operational history - e.g. time since last service, alarm history, degree of utilisation etc. This would allow this information to be accessed by the manufacturer or its agents without physically having access to the pump. This is an advantage where the pumps are spread widely geographically or where access is restricted due to commercial reasons.

The opposite arrangement is also possible where the pump radio circuit 31 captures all the usage information stored within the garment transponder 30 (which could be a history involving many pumps). During servicing of the pump 20 the information is accessed as part of the service procedure.

This sort of information would allow better understanding of the actual pump/garment usage in

healthcare establishments which may provide useful information for commercial, product reliability and quality and clinical efficacy purposes.

The facility to remotely upgrade the operation/ disable use/enable use of the pump is possible.

The pump could include a transponder to self check that its own radio circuit 31 is working and further could be adapted to accommodate an external transponder 50. The transponder 50 in the form of a programming key which when connected to the pump 20, in the vicinity of the radio circuit 31 specifically configures the operation of the pump 20 and garments 21 together as a system for a specific patient in a healthcare environment. This key could be configured by a physician for a particular patient's requirements. The key would override any existing settings stored in the pump and/or garments and ensure that the required pump operation occurred. This would improve patient compliance and product safety and efficacy. Other transponders or similar could be used to log operational data for maintenance purposes.

While the preferred embodiment describes an intermittent garment incorporating a connector having the communication means, it is understood that mattresses as well as any other inflatable and/or deflatable articles may be similarly connected and inflated/deflated using the same principles according to the invention. Moreover, the respective communication means within the article and the pump may be located elsewhere than the connectors as in the preferred embodiment, for example, within the inflatable bladder and/or pump casing. The preferred embodiment has described the connectors using a

means of information exchange incorporating a radio frequency identification device, however any other forms of information exchange devices as discussed earlier or as would be apparent to those skilled in the art are within the scope of the invention.

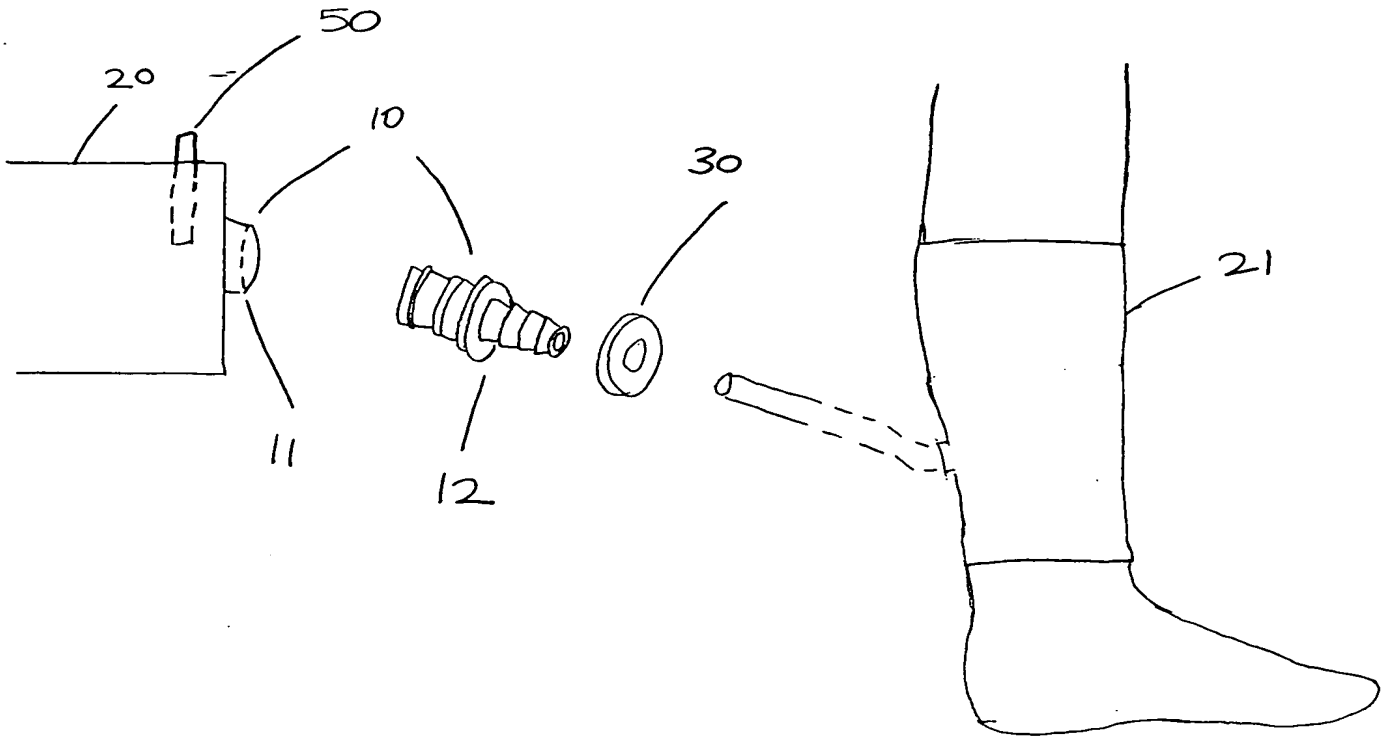


FIGURE 1

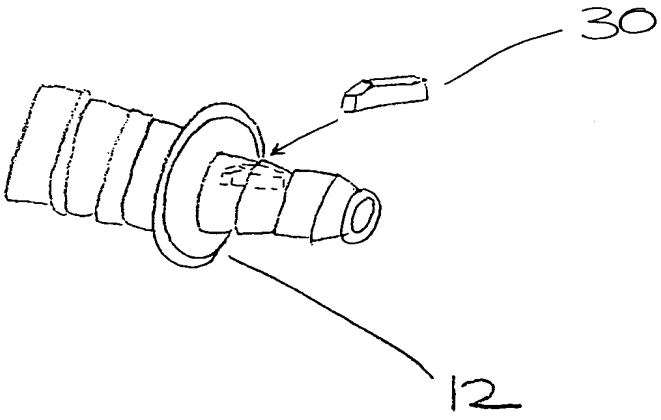
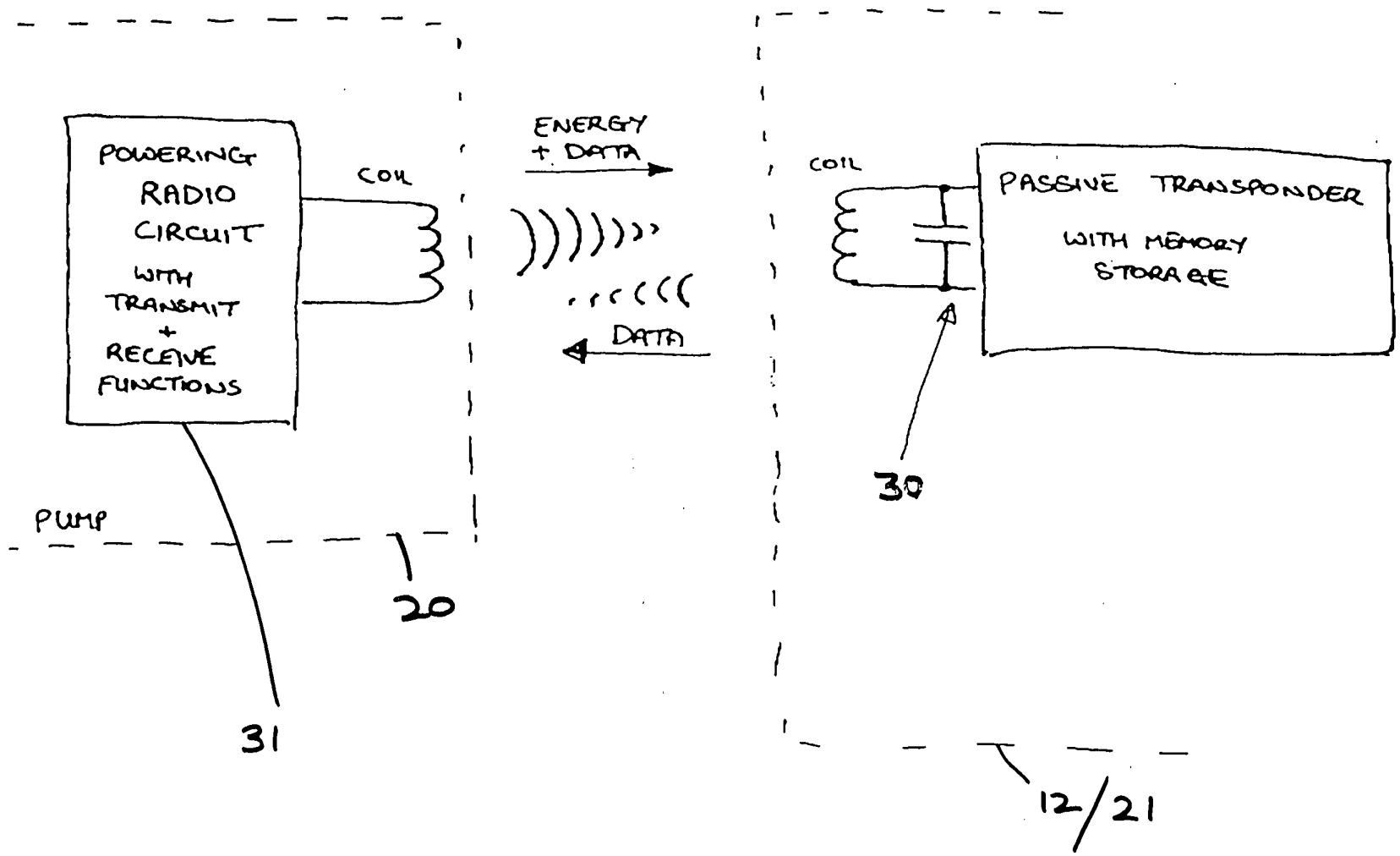


FIGURE 2

FIGURE 3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